K020494

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FEB 21 2002

510(k) Summary.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §.807.92.

1. The submitter of this premarket notification is:

Mike Hudon
Regulatory Approvals Engineer
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1099
Tel.: (978) 659-3173
Fax.: (978) 687-2651

This summary was prepared on November 9, 1998, and updated on February 12, 2002.

2. The name of this device is the M2376A Device Link System. The common name is Device Link. Current Classification is (74) Cardiovascular **MWI**, classification names for the externally connected devices are as follows:

REGULATION NUMBER	CLASSIFICATION NAME	PANEL	PROCODE
870.1110	Computer, blood pressure	Cardiovascular	74 DSK
870.1100	Alarm, blood pressure	Cardiovascular	74 DSJ
870.1130	System, measurement, blood pressure, noninvasive	Cardiovascular	74 DXN
870.2300	Monitor, cardiac	Cardiovascular	74 DRT
876.1800	Urinometer	Gastro-urology	78 EXS
876.5820	System, hemodialysis, access recirculation monitoring	Gastro-urology	78 MQS
880.5725	Pump, infusion	Gnr'l Hospital	80 FRN
870.3535	System, balloon, intra-aortic and control	Cardiovascular	74 DSP
868.5895	Continuous ventilator	Anesthesiology	73 CBK
868.1730	Computer, oxygen uptake	Anesthesiology	73 BZL
870.2700	Oximeter	Cardiovascular	74 DQA
868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology	73 CCK
870.1915	Thermodilution probe	Cardiovascular	74QGL
882.1400	Electroencephalograph	Neurological	84GWQ
868.2375	Breathing Frequency Monitor	Anesthesiology	73 BZQ
880.5400	Neonatal incubator	General Hospital	80 FMZ

870.4360	Cardiopulmonary Bypass Blood Pump	Cardiovascular	74 KFM

3. The M2376A Device Link System receives digital data produced by external devices through device specific cables, converts that data into the HL7 format and transmits that information to any networked Clinical Information System.

4. When connected to a bedside device, the M2376A Device Link System is intended for electronic data collection and clinical information management. Device Link is neither patient connected, nor does it remotely control the attached source device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2002

Mr. Mike Hudon
Regulatory Approvals Engineer
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K020494
Trade Name: M2376A Device Link System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: February 12, 2002
Received: February 13, 2002

Dear Mr. Hudon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

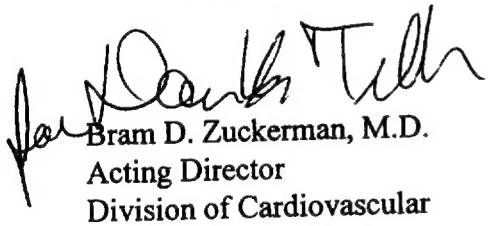
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020494

Device Name: M2376A Device Link System

Indications for Use:

The M2376A DeviceLink System is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices.

The M2376A is not intended for monitoring purposes, nor is the M2376A intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020494

Prescription Use ____X____ **OR** **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)